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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,718	04/09/2004	Clyde L. Schultz	RH01.701US	1509

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EXAMINER	
MAHYERA, TRISTAN J	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
06/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,718	SCHULTZ, CLYDE L.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20 are pending. Claims 15-19 have been withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claim 3' has been cancelled. Claim 1 has been amended. Claim 20 is newly added. Claims 1-14 are examined on the merits.

Specification

The objection to claim 3' is hereby **withdrawn** in light of the claim cancellation.

Claim Rejections - 35 USC § 112 1st Paragraph

The rejection of claims 1-14 is hereby **withdrawn** in light of the claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6 and 9-11 **remain rejected** under 35 U.S.C. § 102(b) as being anticipated by SCHULTZ et al (US 5,723,131). The basis for this rejection can be found in the prior office action.

New Claim 20 is **rejected** under 35 U.S.C § 102(b) as further being anticipated by SCHULTZ et al (US 5,723,131). Desferrioxamine, is an anti-infective agent, specifically an anti-bacterial agent. See e.g. col 2 lines 56-60; instant claim 20.

Claims 1-14 and 20 are **newly rejected** under 35 U.S.C. § 102(e) as being anticipated by SCHULTZ et al (US 2002/0197300) and evidenced by Osborne et al (Brain Research 751 (1997) 113-123). SCHULTZ ('300) teaches a polymeric hydrogel that can absorb an ophthalmic medication for the treatment of glaucoma. See e.g. paragraph [0014]; instant claims 1 and 20. The hydrogel is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate and methacrylate acid. See e.g. claim 13; instant claim 5. The hydrogel has a water content of 10-90% or 38-60% by weight and can be ionic or non-ionic. See e.g. claim 3 and paragraph [0031]; instant claims 2, 3 and 14. The hydrogel can be a contact lens for correcting vision in the range of +8.0 to -8.0 diopters with a base curve from 8.0 to 9.0. See paragraph [0031]; instant claims 10-13. The passive release of a drug into the ocular fluid under ambient and existing conditions is disclosed in claims 5 and 6; instant claims 6 and 9. The drug used is the same as in the instant invention, specifically betaxolol

(see e.g. claim 8); instant claim 4 line 11. Betaxolol is a known neuroprotective (see Osborne et al., Abstract). The reference teaches the same drug in the same hydrogel thus the penetration of the drug to the posterior segment - macula and retina is inherent to the drug: instant claims 7 and 8.

Response to Arguments regarding 35 U.S.C. § 102

Applicant's sole argument is that "[b]acterial infection is outside of the class of posterior segment diseases recited in the pending claims" and thus the use of desferrioxamine, the anti-bacterial agent used in SCHULTZ '131, does not anticipate the instant claims. Applicant's point to the posterior segment diseases provided in paragraph 1 on page 4 of the instant specification. This argument is not found persuasive because on page 4, paragraph 1 line 3, endophthalmitis is listed as an exemplary posterior segment disease. Endophthalmitis is an ocular inflammation resulting from the introduction of an infectious agent into the posterior segment of the eye. See e.g. Callegan et al. "Bacterial Endophthalmitis: Epidemiology, Therapeutics, and Bacterium-Host Interactions" page 111, second column "Bacterial Endophthalmitis".

Claim Rejections - 35 USC § 103

Applicant's remarks have been found persuasive with regard to motivation to combine and the rejection of claims 1-14 is hereby **withdrawn**.

Double Patenting

Applicant's arguments with regard to the **statutory double patenting rejection** of instant claims 1-14 over the claims of copending Application No. 10/971997 are found persuasive and the rejection is hereby **withdrawn**.

Applicant's arguments with regard to the **non-statutory double patenting rejection** of instant claims 1-14 over the claims of Patent No. 7,169,406 are found persuasive and the rejection is hereby **withdrawn**, however, a new rejection follows.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 20 are **newly provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/971,997. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are

directed toward a polymeric hydrogel comprising a drug wherein the drug is capable of treating posterior segment disease. The drug can be a number of agents as listed in instant claims 3 and 4. The hydrogel has a water content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

The '997 claims differ in that the treatment consists of an anti-angiogenesis compound, however, instant claim 20 specifically states the drug can be an angiogenesis inhibitor and VEGF antagonist. Additionally, tamoxifen, thalidomide and VEGF antibodies are stated as the drugs in both applications.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make a polymeric hydrogel for the treatment of posterior segment disease because '997 teaches the use of the same hydrogel and the same drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14 and 20 are **newly rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 13-20 of

U.S. Patent No. 7,169,406. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '406 claims differ from the instant claims (described above) whereby an anti-inflammatory compound is required in claim 1. The compound can be dexamethasone, fluormetholone, rimexolone or prednisolone, which are found in instant claim 4. Therefore, the same hydrogel with the same drugs are taught in both the instant claims and the '406 claims.

Claims 1-14 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 30-34, 38-39, 47, 58 and 60-80 of copending Application No. 11/102454 in view of SCHULTZ (US 6,410,045). The basis for this rejection can be found in the previous office action.

Claims 1-14 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 11, 12, 13, 14, 15 of copending Application No. 10/132843 in view of SCHULTZ (US 6,410,045). The basis for this rejection can be found in the previous office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is

571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615